

Disclosure and Management of Conflicts of Interest

A robust policy on disclosure and management of relevant affiliations and relationships, and of financial interests, is essential for a scientific organization such as the Health Effects Institute. HEI has set out the following policies for disclosure of such ‘conflicts’ – whether actual or perceived, financial or otherwise – and the management and use of this information in managing its funded studies, inviting peer-reviewers and advisors, forming committees, and crafting appropriate roles for committees and their members.

HEI-Funded Investigators

HEI requires investigators to disclose any actual or potential conflicts of interest. Investigators should report financial relationships with entities in the exposure science or environmental health arenas that could be perceived to influence or that give the appearance of potentially influencing the research described in the final report.

Investigators should report all sources of revenue paid (or promised to be paid) directly to them or their institution on their behalf over the past 36 months greater than \$3,000. They should disclose any personal fees (monies paid for services rendered, honoraria, royalties, or fees for consulting, lectures, speakers bureaus, or expert testimony) and nonfinancial support (e.g., reagents, equipment, or travel costs). They should also report any patents – whether planned, pending, or issued – that are broadly relevant to the work and any other relationships or activities, including investment interests (stocks, bonds, and other financial instruments and investments, including partnerships).

Research and Review Committees

In selecting members for its Research and Review Committees, HEI uses disclosure procedures that are similar to those used by the U.S. National Academies. In addition to a letter informing prospective members of HEI’s policies and expectations, HEI uses a two-part form for disclosure of interests. The first part focuses on relationships and affiliations that senior scientists often have with one or more organizations; its major goal is to make such activities known to HEI so that HEI may take this information into consideration – along with myriad other factors – when seeking expert advice. The second part focuses on ‘conflict of interests’ – generally financial in nature – that may be relevant to the member’s work with HEI. Committee members are asked to update such information on a periodic basis. Individuals employed by HEI sponsors may not serve as members of HEI Research or Review Committees. HEI strongly discourages members of its Research and Review Committees from applying for HEI funds as a principal investigator (PI) or co-PI during the term of their committee service. Should a committee member apply for funding, the policies described below apply.

Review of Applications for New Studies

HEI typically reviews applications for new research in a two-step process: Applications are first reviewed by individuals or a panel of experts and then by the Research Committee. For these

purposes, HEI's procedures for managing conflicts of interest are similar to the guidelines set forth by the U.S. National Institutes of Health. Members of HEI's sponsor community are given an opportunity to comment on a draft of the request for application (RFA), but they may not apply for support or participate in application review and funding decisions.

HEI invites external reviewers (or in the case of a major RFA, Application Review Panel members) who do not have a conflict of interest with the proposal(s) they are asked to review. A conflict can occur in a number of ways, including:

- when the reviewer is named on the application in a major professional role;
- the reviewer (or close family member) would receive a direct financial benefit if the application is funded;
- the PI or others on the application with a major role are from the reviewer's institution or institutional component (e.g., department);
- during the past three years the reviewer has been a collaborator or has had other professional relationships (e.g., served as a mentor) with any person on the application who has a major role;
- the application includes a letter of support or reference letter from the reviewer; or
- the reviewer is identified as having an advisory role for the project under review.

In addition, HEI screens external reviewers for potential conflicts of interest with other applicants who have submitted a proposal under the same RFA. Note that a similar policy applies to members of the HEI Research Committee when reviewing applications.

In some situations it may not be possible for members of review panels or Research Committee to avoid all possible conflicts of interest as outlined above. In such cases, the panel or Research Committee members who have a conflict of interest are not assigned to review the application(s) in question and are asked to leave the room during discussion of those application(s). They also do not score or vote on the application(s) at issue and refrain from commenting on them during the overall discussion, and in the case of the Research Committee, from all deliberations regarding recommendation of applications for funding. If several Research Committee members are recused from the overall discussion of applications for such reasons, HEI invites external consultants to join the Committee to fill in the missing areas of expertise.

Site-Visits and Review of Study Progress

HEI uses the same general procedures as those outlined above when seeking experts for site-visits to investigator laboratories or for review of a study's progress. In occasional cases, however, the most appropriate expertise for certain aspects of a study may be found in employees of HEI's sponsors; in such cases, HEI utilizes their expertise for site-visits and review of study's progress.

Review of Final Reports

Final reports from HEI- funded investigators are reviewed in a two- stage process: first a peer review by outside subject-matter experts and then by the Review Committee. HEI uses the same general principles as outlined above for such reviews and for preparation of commentaries. For studies that are particularly large and complex or have direct regulatory significance, HEI may organize a special panel to review the study; the same procedures apply for selection of panel members. Individuals associated with HEI's sponsors may be asked to serve as external reviewers, if they have unique expertise relevant to the study.

Special Reports

For members appointed to panels charged with the preparation of a special report or communication (generally to review the scientific literature in a certain area or to evaluate important research by scientists not sponsored by HEI), HEI adopts the same policies for disclosure of conflicts of interest as for the appointment of Research or Review Committee members. HEI also subjects the reports prepared by such panels to peer-review, using the same general procedures for conflicts as described above for external reviews. However, panel reports may be sent for review to individuals whose work has been reviewed in the report or who have expressed specific views on the work being reviewed by the panel.

Special Committee on Emerging Technologies

In appointing members to the Special Committee on Emerging Technologies and Fuels, or other similar committees or workgroups that advise HEI on its science and technical efforts but have no role in selecting, overseeing, or reviewing studies, HEI may appoint some members who are current or former employees of HEI's sponsors or other companies, or who represent other groups with acknowledged interests (such as trade associations or public interest groups).

Role of the HEI Board of Directors

The HEI Board has the ultimate authority for appointment of members to the Research or Review Committees. When considering prospective members, the Board ensures that the member has provided full disclosure and that the conflicts, if any, can be managed.

The Board is also responsible for approval of scientific studies as well as research or special reports. The Board generally defers to the scientific expertise, judgment and decisions by the Committees; however, in giving its approval the Board pays close attention to the processes used by HEI and its committees, including the steps taken to avoid and manage conflict of interests.

Disclosures and decisions in these and other situations are a matter of professional judgment, and it is not possible to describe all potential scenarios. HEI relies on its committee members and reviewers to declare to HEI the existence of any real or apparent conflict of interest. If a committee member or reviewer feels unable to provide objective advice for any other reason, he/she is expected to recuse him/herself from the review of that application(s) or report(s). For any questions, please consult with HEI's Director of Science or President.